UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALASKA ELECTRICAL PENSION FUND, et al., Plaintiffs, -against- PHARMACIA CORPORATION., et al., Defendants.	03-CV-1519 (AET) (Consolidated) **ORAL ARGUMENT REQUESTED** DOCUMENT FILED ELECTRONICALLY

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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Defendants Pharmacia Corporation ("Pharmacia", or, the "Company"), Pfizer, Inc. ("Pfizer"), Fred Hassan, Dr. G. Steven Geis, and Carrie Cox (collectively, the "Defendants") submit this memorandum of law in support of their motion for summary judgment pursuant to Fed. R. Civ. P. 56, for judgment as a matter of law on all claims in the complaint filed in this action (the "Complaint").

PRELIMINARY STATEMENT

The April 7, 2003 Complaint in this action alleges that Defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), and Rule 10b-5 promulgated thereunder, by misrepresenting the results of a clinical drug study – the Celecoxib[1] Long-Term Arthritis Safety Study ("CLASS") – concerning the drug Celebrex®.

On January 25, 2007, the Court certified a class consisting of purchasers of Pharmacia common stock during the period April 17, 2000 to February 6, 2001. The Court selected February 6, 2001 as the end date for the class period because, on that date, the United States Food and Drug Administration (the "FDA") published information on its website that was "curative" of any prior alleged misrepresentations about the CLASS study that were made by Defendants in earlier press releases and in an article published on September 13, 2000 in the Journal of the American Medical Association ("JAMA"). January 25 Op. at 7. The Court, therefore, found that Plaintiffs and the class were on inquiry notice of any alleged fraud regarding the results of the CLASS study no later than February 6, 2001, and no subsequent purchasers of Pharmacia stock could reasonably have relied on the earlier alleged misrepresentations. *Id.* This finding was supported by undisputed record evidence, including the

[1] Celecoxib is the generic name for Celebrex®. Celebrex is a COX-2 inhibitor drug prescribed for the treatment of symptoms associated with osteoarthritis and rheumatoid arthritis.

uncontroverted opinion of Defendants' expert, Dr. Timothy Cragin Wang. Plaintiffs petitioned the Third Circuit for an interlocutory appeal to challenge the Court's designation of February 6, 2001 as the end date of the class period, but, on March 28, 2007, the Third Circuit denied Plaintiffs' petition.

The analysis underlying this Court's decision on class certification is equally applicable to the conclusion that Plaintiffs' and the class's claims are time barred. Under Sections 10(b) and 20(a) of the Exchange Act, Plaintiffs were required to bring this action no later than two years from the date on which they were on "inquiry notice," that is, when they had, or should have had, reason to believe that Defendants' statements regarding the results of CLASS were false or misleading. Stated differently, an investor is on inquiry notice of alleged fraud "whenever circumstances exist that would lead a reasonable investor of ordinary intelligence, through the exercise of reasonable diligence, to discover his or her injury." Here, as the Court has already found, Plaintiffs and the class were put on inquiry notice of Defendants' alleged fraud by the information posted on the FDA website on February 6, 2001, and the widely disseminated recommendation of the FDA Arthritis Advisory Committee to reject Defendants' request for a change in the standard gastrointestinal warning label for Celebrex. This action was not commenced, however, until April 7, 2003, more than two years after February 6, 2001. Because Plaintiffs have not brought their claims within the applicable limitations period, Defendants are entitled to summary judgment as a matter of law.

This case is virtually identical to *In re Merck & Co. Securities, Derivative & "ERISA" Litigation*, MDL No. 1658, C.A. Nos. 05-1151, -2367, 2007 WL 1100820 (D.N.J. Apr. 12, 2007), recently decided by Judge Chesler. There, plaintiffs alleged that Merck misrepresented the safety profile of Merck's drug VIOXX by concealing information indicating that it increased the risk of cardiovascular adverse events. *Id.* at *8. However, more than two

years prior to the filing of the complaint, the FDA issued a "warning letter" to Merck that certain advertising did not accurately describe the cardiovascular risks associated with VIOXX. *Id.* at *5. That warning letter was published on the FDA website and "received widespread media and analyst coverage." *Id.* Judge Chesler dismissed the plaintiffs' claims as time barred because the plaintiffs were on inquiry notice of the facts underlying their claims more than two years prior to the filing of the complaint, as a result of the information published on the FDA website. *Id.* at *17. For the same reasons, Plaintiffs' complaint in this action should be dismissed.

FACTS[2]

Celebrex® is an NSAID (nonsteroidal anti-inflammatory drug), used primarily to alleviate the pain and inflammation caused by arthritis. Dreier Decl., Ex. 1 ¶ 2; SUF ¶ 8. Unlike traditional generic NSAIDs, which inhibit both the COX-1 and COX-2 enzymes, Celebrex® is a selective COX-2 inhibitor, which previous studies had shown to have a superior gastrointestinal ("GI") safety profile than traditional NSAIDs. The FDA, however, requires that all NSAIDs carry a warning label alerting physicians and consumers to, among other things, the potential GI side-effects associated with those medications. Dreier Decl., Ex. 1 ¶ 3; SUF ¶ 9. To support a supplemental New Drug Application ("sNDA") for FDA approval of revised labeling without the Standard GI Warning for NSAIDs (the "Standard GI Warning"), Pharmacia commissioned CLASS. Dreier Decl., Ex. 1 ¶ 4; SUF ¶ 10.

A. The CLASS Study

The protocol, or design, for CLASS specified that Celebrex® would be compared to two commonly used traditional NSAIDs, ibuprofen and diclofenac. Dreier Decl., Ex. 1 ¶ 5;

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[2] The supporting material for the facts set forth herein are contained in and attached to the accompanying Declarations of William A. Dreier, dated May 25, 2007 and Dr. Timothy Cragin Wang, dated May 29, 2007 ("Dreier Decl." and "Wang Decl.," respectively), and in the accompanying Local Rule 56.1 Statement of Undisputed Facts ("SUF").

SUF ¶ 11. The protocol contemplated both primary and secondary "endpoints," or bases for comparison, of Celebrex to ibuprofen and diclofenac. Dreier Decl., Ex. 14 at 14; SUF ¶ 12. The primary endpoint was to be made by reference to the incidence of "ulcer complications" – defined, for purposes of the Study, as upper gastrointestinal bleeding, perforation or gastric outlet obstruction in patients with osteoarthritis or rheumatoid arthritis. A secondary pre-defined endpoint was the incidence of "symptomatic ulcers" – defined, for purposes of the Study, as ulcers identified based on upper gastrointestinal symptoms such as abdominal pain, dyspepsia, nausea, diarrhea or vomiting and confirmed by endoscopic observation of the gastrointestinal tract. *See* Dreier Decl., Ex. 2 at 1249; SUF ¶ 12.

The study ran from approximately September 1998 to March 2000. Dreier Decl., Ex. 2 at 1247; SUF ¶ 13. The results showed that Celebrex did not meet the primary endpoint. Dreier Decl., Ex. 1 ¶ 46; *id.*, Ex. 2 at 1254; SUF ¶ 14. In other words, when considering the entirety of the data, there was no statistically significant difference in the incidence of ulcer complications between the group of patients taking Celebrex and the group of patients taking the NSAIDs. Dreier Decl., Ex. 1 ¶ 46; *id.*, Ex. 2 at 1254; SUF ¶ 14. In light of the failure to meet the primary endpoint and the identification of potential biases introduced by patient withdrawals, Pharmacia scientists undertook various alternative analyses of the CLASS data that were not pre-specified in the original study protocol. Dreier Decl., Ex 13 at 6; SUF ¶ 15. In that regard, the alternative analyses included considering only the first 6 months of data from the study and using an expanded primary endpoint, which included the incidence of both symptomatic ulcers and ulcer complications. Dreier Decl., Ex 13 at 12; SUF ¶ 15. According to the alternative analyses, there were indications of a safety advantage for Celebrex.

B. Announcement Of The CLASS Results

On or about April 15, 2000, the results of CLASS were announced at the annual meeting of the American College of Physicians. Dreier Decl., Ex. 1 ¶ 36; SUF ¶ 16. Two days later, on April 17, 2000, Pharmacia issued a press release concerning the results of the CLASS Study. Dreier Decl., Ex. 1 ¶ 36; SUF ¶ 16. According to that Release:

> In a landmark study to assess the overall long-term safety of the COX-2 specific inhibitor Celebrex® (celecoxib capsules), arthritis patients taking four times the recommended osteoarthritis (OA) dose of the drug experienced fewer symptomatic gastrointestinal (GI) ulcers and ulcer complications than patients taking ibuprofen and diclofenac – a difference that was statistically significant based on a combined analysis of Celebrex® versus these two traditional nonsteroidal anti-inflammatory drugs (NSAIDs).

Dreier Decl., Ex. 3 at 1; SUF ¶ 16.

The Release did not claim that CLASS demonstrated that Celebrex was superior to the NSAIDs with respect to the incidence of ulcer complications alone (the pre-specified primary endpoint), but stated clearly that the conclusions were based on the expanded endpoint of the combined incidence of symptomatic ulcers and ulcer complications. Dreier Decl., Ex. 3 at 1; SUF ¶ 17. The Release disclosed that CLASS was "an approximately 13-month study" that "'included a large number of patients who received four times the recommended [osteoarthritis] dose of Celebrex® for up to 13 months.'" Dreier Decl., Ex. 3 at 2, 3 (citation omitted); SUF ¶ 18. The fact that CLASS "took place over 13 months" was also reflected in two Dow Jones News Service articles published on April 17, 2000. Dreier Decl., Exs. 4, 5; SUF ¶ 19 . The April 24, 2000 edition of the "Pink Sheet," a widely utilized and publicly available Pharmaceuticals industry newsletter, also reported that although CLASS was a "13-month double-blind . . . trial . . . . **[D]ata from the first six months of the trial** were used for the head-to-head comparison of NSAIDs . . . ." Dreier Decl., Ex. 6 at 2 (emphasis added); SUF ¶ 20. On

May 23, 2000, the Company issued another press release (the "May 23, 2000 Press Release") that reiterated the Company's prior disclosure that CLASS spanned 13 months. Dreier Decl., Ex. 7 at 2; SUF ¶ 21.

The failure of CLASS to demonstrate a superior safety profile for Celebrex with respect to the primary endpoint and the basis for Pharmacia's conclusions based on the alternative analysis were well understood by the market. Dreier Decl., Exs. 8, 9, 10. For example, on April 17, 2000, J.P. Morgan Securities published to the market a report on CLASS stating that "[f]or the endpoint 'ulcers and complications' . . . Celebrex was statistically superior . . . . However for the higher hurdle, 'complications' only, Celebrex . . . miss[ed] statistical significance . . . . Unfortunately, this was the predefined 'primary endpoint' of the trial." Dreier Decl., Ex. 8; SUF ¶ 22. A report issued on April 18, 2000 by Morgan Stanley Dean Witter stated that "the trial did not demonstrate statistically significant superiority of Celebrex in the primary endpoint of ulcer complications . . . . However, on the second endpoint of ulcer complications *plus* symptomatic ulcers, Celebrex was shown to be statistically superior to NSAIDs." Dreier Decl., Ex. 9 at 2 (emphasis in original); SUF ¶ 23.

C. Submission Of CLASS Data To The FDA

On or about June 12, 2000, in connection with Pharmacia's application to the FDA to modify the Standard GI Warning Label for NSAIDs in the Celebrex® label, Pharmacia submitted data for the entire CLASS Study to the FDA. *See* Dreier Decl., Ex. 11; SUF ¶ 24. Pharmacia also submitted to the FDA Arthritis Advisory Committee (an advisory committee comprised of FDA-appointed, independent experts (the "Arthritis Advisory Committee")) a "Briefing Document" which set forth, among other things, several analyses of the CLASS data. *See* Dreier Decl., Ex. 13 at 1; *id.*, Ex. 14 at 1; SUF ¶ 25. These analyses included: (1) an analysis as specified in the original study protocol, that is, based upon data from the entire study period

and the original primary endpoint, and (2) an alternative analysis based upon six months of data and the expanded endpoint (symptomatic ulcers and ulcer complications). Dreier Decl., Ex. 12; SUF ¶ 26. The Briefing Document explained Pharmacia's view that the alternative analysis at six months minimized the bias introduced in the Study data over time by a disproportionately larger number of patients in the NSAID arms who dropped out of the study for GI events that did not amount to a complicated ulcer:

> The GI safety data presented are for the six-month treatment timepoint based on the analysis of risk factors prespecified in the protocol. In brief, a disproportionate withdrawal of patients at high risk of an ulcer complication from the entire study was observed after six months (depletion of susceptibles). Additionally, a significantly greater withdrawal of patients on diclofenac for GI intolerance occurred during the initial six months of the study. The withdrawal of patients for GI intolerance prematurely removed a group at high risk for ulcer complications and symptomatic ulcers from the diclofenac treatment arm (informative censoring).

Dreier Decl., Ex. 12 at 28; SUF ¶ 27.

D. <u>The JAMA Article And The FDA Staff Review Documents</u>

On September 13, 2000, Defendant Geis and 15 other doctors and scientists – ten of whom were not Pharmacia employees and are experts in their fields and affiliated with prestigious universities and other institutions – published an article regarding the results of CLASS in the JAMA (the "JAMA Article"). Dreier Decl., Ex. 1 ¶ 45; *id.*, Ex. 2; SUF ¶ 28. Consistent with the alternative analysis presented in the Briefing Document, the JAMA Article stated that the "Main Outcome Measure" being used for purposes of the article was the "[i]ncidence of . . . symptomatic upper GI ulcers and ulcer complications . . . during the 6-month treatment period." Dreier Decl., Ex. 2 at 1247; *id.*, Ex. 1 ¶ 45; SUF ¶ 29. On that basis, the JAMA Article concluded that "[t]he study determined that [Celebrex®] when used for 6 months . . . is associated with lower incidence of combined clinical upper GI events than Comparator

NSAIDs (ibuprofen and diclofenac) . . . ." Dreier Decl., Ex. 2 at 1253-54; SUF ¶ 29. The JAMA Article, however, acknowledged that "the rate for ulcer complications did not differ" significantly between the Celebrex® patients and the NSAID patients – in other words, that Celebrex® failed to demonstrate statistically significant superiority in terms of the primary endpoint. Dreier Decl., Ex. 2 at 1254; SUF ¶ 29.[3]

On February 6, 2001, the FDA posted to its website[4] (SUF ¶ 30) the Briefing Document, as well as reports by two medical officers employed by the FDA (the "FDA Medical Officers") and a statistician employed by the FDA (the "FDA Statistician"), who analyzed CLASS data from the entire study period that had been submitted to the FDA (the "FDA Staff Review Documents")[5]; SUF ¶ 31. In the FDA Staff Review Documents, the FDA Medical Officers and the FDA Statistician expressed their disagreement with the alternative analysis set forth in the JAMA Article and the Briefing Document, calling it "not valid," and "not convincing," and opined that "the most critically relevant analysis covers the complete study period as specified in the original protocol." Dreier Decl., Ex. 15 at 8-9; *id.*, Ex. 13 at 14, 24; SUF ¶ 32. In particular, Dr. Goldkind stated that "after the study ended the sponsor added a new

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[3] An editorial published in the same edition of JAMA also noted that Celebrex failed to satisfy the primary endpoint of CLASS. Dreier Decl., Ex. 49.

[4] *See* http://www.fda.gov/ohrms/dockets/ac/01/briefing/3677b1.htm (last visited May 25, 2007). The Court may take judicial notice of documents posted on the FDA website. *See In re AgriBiotech Sec. Litig.*, CV-S-990144 PMP, 2000 U.S. Dist. LEXIS 5643, at **4-5 (D. Nev. Mar. 2, 2000) ("In this new technological age, official government or company documents may be judicially noticed insofar as they are available via the worldwide web"); *Modesto Irrigation Dist. v. Pacific Gas & Elec. Co.*, 61 F. Supp. 2d 1058, 1066 (N.D. Cal. 1999) (taking judicial notice of document "readily accessible through the internet"), *rev'd on other grounds*, 54 Fed. Appx. 882 (9th Cir. 2002); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003) ("[T]he Court will take judicial notice of the FDA's Center for Drug Evaluation and Research Listing of . . . Drug Approvals").

[5] The FDA Staff Review Documents consist of: *Medical Officer's Gastroenterology Advisory Committee Briefing Document* by Lawrence Goldkind, M.D. ("Goldkind Review") (Dreier Decl., Ex. 13), *Medical Officer Review* by James Witter, M.D., Ph.D ("Witter Review") (Dreier Decl., Ex. 14) and *Statistical Reviewer Briefing Document for the Advisory Committee* by Hong Laura Lu, Ph.D. ("Lu Review") (Dreier Decl., Ex. 15).

set of analyses that was based on the first six months of [sic] study instead of the entire study period," and opined that "[t]he sponsor has not adequately justified . . . replacing the original analysis with this post hoc analysis." Dreier Decl., Ex. 13 at 23; SUF ¶ 33.

The FDA Medical Officers also noted that use of an expanded endpoint was not pre-specified in the protocol (that is, "the inclusion of a combined analysis of CSUGIEs and GDU[6] **was a post-hoc decision** . . ." Dreier Decl., Ex. 13 at 21 (bold emphasis added; underscore in original); SUF ¶ 34) and pointed out that the alternative analysis was not in conformity with the pre-specified statistical analysis plan because it was based upon only a comparison of Celebrex to the NSAIDs combined, and not individually. In that regard, Dr. Goldkind explained that "comparisons to each of the NSAID comparators were defined in the original protocol," and that "[t]he clinical importance of statistically significant superiority to each of the comparators was reflected in the statistical plans in the **original protocol**." Dreier Decl., Ex. 13 at 7 (bold and underline emphasis in original); SUF ¶ 35.

The FDA Medical Officers further explained that, when analyzed according to the original CLASS protocol, "Celecoxib did not demonstrate statistical superiority to NSAIDs (pooled) or either comparator . . . with regards to the primary safety endpoint . . . at any point in the trial." Dreier Decl., Ex. 14 at 82; s*ee also id.* at 48 ("**[a]nalysis of the entire study period** showed that the difference between celecoxib and pooled NSAIDs for CSUGIEs in the entire study population was not statistically significant") (emphasis in original); Dreier Decl., Ex. 13 at 52 ("[t]he sponsor has failed to demonstrate a statistically significant lower rate of CSUGIEs

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[6] "CSUGIE" is an acronym for Clinically Significant Upper Gastrointestinal Event and is synonymous with "ulcer complications," the predefined primary endpoint. "GDU" stands for gastroduodenal ulcers and is synonymous with "symptomatic ulcers," the secondary endpoint.

(traditional or alternate) compared to NSAIDs as a group or either individual comparator"); SUF ¶ 36.

Finally, the FDA Medical Officers and the FDA Statistician publicly disagreed with Pharmacia's rationale for employing the alternative analysis. In that regard, Dr. Goldkind wrote that Pharmacia "has not adequately justified the value of an analysis limited to 6-month data nor adequately justified replacing the original analysis with this post-hoc analysis." Dreier Decl., Ex. 13 at 23. Dr. Lu, the FDA Statistician, concurred: "[Pharmacia's] rationale for analyzing the first 6 months of data only is that the large dropout rate in the later stages of the study depleted high-risk patients . . . . **This rationale is not valid** . . . ." Dreier Decl., Ex. 15 at 8 (emphasis added); SUF ¶ 37.

The FDA Staff Review Documents were analyzed and their substance reported on immediately in both the financial and mainstream press. For example, in a February 7, 2001 report entitled "FDA Review of Celebrex More Negative Than Expected – Panel Could Be Controversial," J.P. Morgan Securities reported that, according to the FDA Reviewers, "Pharmacia's analysis of data at only the 26 week [6 month] time point, rather than the 52 week time point, is unjustified and invalid." Dreier Decl., Ex. 16 at 2; SUF ¶ 38. The same J.P. Morgan Securities report noted that "[b]oth the Gastrointestinal Reviewer [Goldkind] and the Statistical Reviewer [Lu] so strongly disagreed with Pharmacia's analysis of the data at the 26 week time point that both specifically did not discuss or treat those results, focusing instead their entire discussion on the end-of-study data," and summarized in detail the reasons given in the Goldkind Review for rejecting the six month analysis. Dreier Decl., Ex. 16 at 3; SUF ¶ 38. A similar report published on the Bloomberg newswire reported that, according to the FDA reviewers, "only by looking at selected parts of the data – a practice discouraged by the agency –

was the company able to show a benefit [for Celebrex]." Dreier Decl., Ex. 17; *see also id.*, Exs. 18, 19, 20; SUF ¶ 39.

E. The FDA Arthritis Advisory Committee Meeting

On February 7, 2001, the Arthritis Advisory Committee held a public hearing to consider the results of CLASS in connection with Pharmacia's request to remove or modify the Standard NSAID GI Warning from the Celebrex® label.[7] SUF ¶ 40. At that hearing, representatives from Pharmacia and from the FDA staff made presentations to the Advisory Committee regarding the results of CLASS. The presentations made clear that CLASS lasted longer than 6 months, the original primary endpoint did not include symptomatic ulcers, and, when analyzed according to the original protocol, there was no statistically significant difference between Celebrex and the comparator NSAIDs with respect to the primary endpoint. Members of the public were also permitted to attend and comment. *See* Dreier Decl., Ex. 21 at 56-60, 104, 108-109, 115, 169-170, 175-176; SUF ¶ 41.

At the conclusion of the public hearing, the Arthritis Advisory Committee recommended that the Standard NSAID GI Warning remain in the Celebrex® label.[8] Dreier Decl., Ex. 22 at 1; SUF ¶ 42. This recommendation and the substance of the presentations were widely reported in analyst reports and the press. *See* Dreier Decl., Exs. 23, 24; SUF ¶ 43. For

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[7] A transcript of the February 7, 2001 Arthritis Advisory Committee public hearing was made publicly available on the FDA website in or about March 2001. *See* http://www.fda.gov/ohrms/dockets/ac/01/transcripts/3740t1_01.pdf (last visited May 25, 2007) (excerpts of the transcript are attached as Dreier Decl., Ex. 21).

[8] Notably, however, the FDA did not entirely follow its Advisory Committee's recommendation in this regard, and ultimately approved a modification to the Celebrex warning label based on favorable data from CLASS. Dreier Decl., Ex. 22; SUF ¶ 49. Thus, on June 7, 2002, the FDA announced that "[t]he FDA has approved labeling change for Celebrex . . . based on the results of the . . . CLASS [Study] . . . The Agency . . . determined that valuable safety data from CLASS should be incorporated into the labeling." Dreier Decl., Ex. 22 at 1; SUF ¶ 50. The "valuable safety data" that was incorporated into the labeling included the results from the CLASS Study at 9 months and showed results based on both the primary endpoint of complicated ulcers and the combined endpoint of symptomatic ulcers and complicated ulcers. *See* Dreier Decl., Ex. 22 at 1; *see also id.*, Ex. 50; SUF ¶ 51.

example, as noted in a February 8, 2001 Chicago Tribune article, "[CLASS] did not sway a Food and Drug Administration panel. Committee members said they saw no edge for Celebrex over treatments such as ibuprofen when comparing rates of the most serious ulcers." Dreier Decl., Ex. 23; SUF ¶ 44. A February 8, 2001 Merrill Lynch Analyst Report entitled "CLASS Trial – Something Ventured, Nothing Gained," also reported that the Committee "recommended that the FDA not relax the current warnings found in the Celebrex label with regard to gastrointestinal side-effects." Dreier Decl., Ex. 24; *see also id.*, Exs. 25-41; SUF ¶ 45.

F. The Public Controversy Over The JAMA Article

After the Briefing Document and the FDA Staff Review Documents were posted on the FDA website and the Arthritis Advisory Committee public hearing was held, certain commentators criticized the JAMA Article, claiming that it did not accurately present the results of CLASS. Dreier Decl., Ex. 1 ¶ 64; *id.*, Exs. 42-46; SUF ¶ 47. These criticisms included letters from medical professionals (including Dr. James Wright, one of Plaintiffs' expert witnesses in this action) published in medical journals and media reports. Dreier Decl., Ex. 42; SUF ¶ 48. These criticisms were all based on those commentators' review of the FDA Staff Review Documents and the Briefing Document that were posted on the FDA website on February 6, 2001 and their comparisons of the data presented in those documents to that published in the JAMA Article. Dreier Decl., Exs. 42-46; SUF ¶ 48. In general, these commentators complained that the data and analyses presented in the widely publicized Briefing Document and the FDA Staff Review Documents indicated that the alternative analysis presented in the JAMA Article did not accurately describe the results of CLASS because it was based upon only six months of data and an expanded endpoint that was not pre-specified. *See* Dreier Decl., Ex. 42; *id.*, Ex. 43 at 1131; *id.*, Ex. 44 at 2; *id.*, Ex. 45 at 1-2; *id.*, Ex. 46 at 3; SUF ¶ 48.

ARGUMENT

It is well established that summary judgment should be granted when no material triable issues of fact exist. *Mathews v. Kidder, Peabody & Co.*, 260 F.3d 239, 250 (3d Cir. 2001) (affirming summary judgment dismissing claims as time-barred where there was no "genuine issue of material fact surrounding" when the plaintiffs were on inquiry notice of their claims). Here, the undisputed evidence establishes that, as this Court has already found, Plaintiffs and the class were on inquiry notice of the basis for their claims no later than February 6, 2001, when "curative" information was posted on the FDA website. January 25 Op. at 7. Because Plaintiffs did not file their complaint until April 7, 2003, well after the expiration of the two year statute of limitations period, the Court should grant summary judgment to the Defendants as a matter of law. *See Leibholz v. Hariri*, C.A. No. 05-5148, 2006 WL 2023186, at *7 (D.N.J. July 12, 2006) (granting summary judgment dismissing securities fraud claims as time-barred).

A. Plaintiffs Were Required To File Their Claims Within Two Years Of Receiving Inquiry Notice Of The Facts Underlying Their Claims

A claim for securities fraud under Sections 10(b) and 20(a) of the Exchange Act must be brought no later than the earlier of "(1) 2 years after the discovery of the facts constituting the violation; or (2) 5 years after such violation." 28 U.S.C. § 1658(b). In order to be timely, a plaintiff must file an "action within two years of discovering sufficient facts regarding the alleged fraud." *Osio v. DeMane*, Nos. Civ. A. 05-2283, -2280, 2006 WL 2129460, at *5 (D.N.J. July 24, 2006). It is not necessary for a plaintiff to have "actual knowledge or know all of the details of the alleged fraud to trigger the [running of the] limitations period." *In re Merck*, 2007 WL 1100820, at *10 (*citing In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1325-27 (3d Cir. 2002)). Rather, the statute of limitations begins to run "when the plaintiff 'discovered or in the exercise of reasonable diligence should have discovered the basis for [his] claim against the defendant.'" *Leibholz*, 2006 WL 2023186, at *7 (citation omitted). Thus, an

investor is on inquiry notice of alleged fraud "whenever circumstances exist that would lead a reasonable investor of ordinary intelligence, through the exercise of reasonable diligence, to discover his or her injury." *Mathews*, 260 F.3d at 251. "Whether the plaintiffs, in the exercise of reasonable diligence, should have known of the basis for their claims depends on whether they had 'sufficient information . . . to excite "storm warnings" of culpable activity.'" *In re Exxon Mobil Corp. Sec. Litig.*, 387 F. Supp. 2d 407, 417 (D.N.J. 2005) (*quoting In re NAHC*, 306 F.3d at 1325) (other citations omitted). "Storm warnings" include "'the accumulation of information over a period of time that conflicts with representations that were made when the securities were originally purchased, or any financial, legal or other data that would alert a reasonable person to the probability that misleading statements or significant omissions had been made.'" *In re NAHC*, 306 F.3d at 1326 n.5 (*quoting Mathews*, 260 F.3d at 252). "Plaintiffs cannot avoid [inquiry notice] simply by claiming they lacked knowledge 'of the details or "narrow aspects" of the alleged fraud' . . . . Rather [they are on inquiry notice] when they '"should have discovered the general fraudulent scheme."'" *Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 400 (3d Cir. 2006) (*quoting In re NAHC*, 306 F.3d at 1326; *citing Mathews*, 260 F.3d at 252) (other citations omitted). In this case, there were not merely "storm warnings;" there was a "hurricane" of actual published scientific data and debate, and investment analyst commentary on the very subjects alleged to have been fraudulently misrepresented by the Defendants, more than two years prior to the filing of the Complaint.

Once a defendant establishes that a plaintiff was on inquiry notice of the facts underlying his or her claims, "the burden then shifts to the plaintiffs to demonstrate that they were unable to discover their injuries despite the exercise of reasonable due diligence." *In re Merck*, 2007 WL 1100820, at *10. Plaintiffs must demonstrate that they "undertook their duty to investigate the basis for their claims but nevertheless failed to discover information necessary to

initiate a securities fraud action." *Id.* Plaintiffs may not avoid their duty to investigate; """if storm warnings existed, and the plaintiffs choose not to investigate, [the court] will deem them on inquiry notice of their claims."" *Id.* (*quoting Benak*, 435 F.3d at 401 (*quoting Mathews*, 260 F.3d at 252 n.16)).

Recently, Judge Chesler dismissed Section 10(b) claims as time barred under circumstances virtually identical to this action. The plaintiffs in *Merck* alleged that Merck fraudulently concealed information indicating that Merck's drug VIOXX increased the risk of cardiovascular adverse events. 2007 WL 1100820, at *8. However, more than two years prior to filing the complaint, the FDA issued a "warning letter" to Merck in which it cautioned Merck that certain advertising did not accurately describe the cardiovascular risks associated with VIOXX. *Id.* at *5. That warning letter was published on the FDA website and "received widespread media and analyst coverage." *Id.* On this basis Judge Chesler found that "[g]iven that the FDA Warning Letter was published on September 21, 2001, and that it received a substantial amount of attention from the media and financial analysts immediately following its publication, the Court finds that it is clear that storm warnings of fraud by the company existed more than two years before this Complaint was filed." *Id.* at *17.

Similarly, in *Exxon Mobil*, the plaintiffs alleged that Exxon artificially inflated the value of its stock by failing to recognize in its financial statements certain impairments to "the long-term carrying value of Exxon's oil and gas assets." 387 F. Supp. 2d at 411. The court found that the plaintiffs were on inquiry notice of the alleged overstatement of those assets because "the public information regarding impairments taken by other oil and gas companies directly contradicted Exxon's actions of not reporting" the impairments. *Id.* at 418. The public information "provided the 'red flags' that should have alerted [the] [p]laintiffs to the possibility that [the] [d]efendants made misleading statements or significant omissions regarding the true

nature of Exxon's financial condition." *Id.* Because the plaintiffs did not file their claims within the limitations period – which began to run once the plaintiffs were on inquiry notice – the securities fraud claims were dismissed as time-barred. *Id.* at 419.

B. Plaintiffs Were On Inquiry Notice No Later Than February 6, 2001 But Failed To Timely File Their Complaint Within The Two Year Statute Of Limitations

Here, as this Court has already determined, the February 6, 2001 publication on the FDA website of the Briefing Document and the FDA Staff Review Documents, the Arthritis Advisory Committee public hearing and the substantial and contemporaneous media and financial analyst coverage of these materials and proceedings, likewise constituted "storm warnings" that put Plaintiffs and the class members on inquiry notice of Defendants' alleged misrepresentations.[9] In the January 25 Opinion, the Court found that "the FDA's data release and the advisory committee ruling . . . constituted a curative disclosure as they were substantial, widely-reported, and contradicted the Defendants' conclusions about the results of CLASS." January 25 Opinion at 7.[10] In reaching that conclusion, the Court noted that "[c]urative

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[9] The FDA Staff Review Documents analyzed the Briefing Document and critiqued Defendants' presentation of the CLASS results on precisely the same basis underlying Plaintiffs' claim that the JAMA Article was false and misleading. Indeed, the storm warnings here are even clearer than in *Merck*, because, as discussed herein, the Briefing Document and the FDA Staff Review Documents publicly revealed curative information about each of the specific alleged misrepresentations more than two years prior to the filing of the complaint. In *Merck*, the warning letter issued by the FDA addressed the general sufficiency of the disclosures in Merck's advertising for VIOXX.

[10] Under the law of the case doctrine, once decided by a court, an issue "may not be relitigated in the same case." *Speeney v. Rutgers*, C.A. Nos. 02-959, -960, -961, -963, 2006 WL 3257059, at *3 (D.N.J. Nov. 9, 2006) (granting summary judgment on the grounds that the issue of the existence of an attorney-client relationship had already been "resolved by [the] [c]ourt after reviewing all the evidence and arguments set forth by the parties" in an earlier hearing). When "a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages of the same case." *In re Complaint of Weeks Marine, Inc.*, C.A. No. 04-0494, 2006 WL 2987090, at *3 (D.N.J. Oct. 17, 2006); *Spagnola v. Town of Morristown*, C.A. No. 05-577, 2006 WL 3533726, at *5 (D.N.J. Dec. 7, 2006) (dismissing a claim because the court's earlier decision regarding whether or not the defendant was a state actor "now constitutes [the] 'law of the case' and as such will not be disturbed for purposes of the present motion"). Thus, Plaintiffs are precluded from contesting, in connection with this motion, the Court's

information retracts or dispels the alleged misinformation, or puts the investor **on inquiry notice** of the alleged fraud, making further reliance on the original statements by investors unreasonable." *Id.* (emphasis added).

The standard for when a class period must end in a securities fraud action and the standard for when the statute of limitations for securities fraud begins to run are the same: when a plaintiff is on inquiry notice. It is axiomatic that a class period cannot extend beyond the date when "the facts which underlie the gravamen of the plaintiff's complaint" are revealed so that a reasonable investor would no longer rely on the defendants' misrepresentations. *Vitiello v. Cicconi* (*In re Data Access Sys. Sec. Litig.*), 103 F.R.D. 130, 143 (D.N.J. 1984). Similarly, the statute of limitations begins to run when "disclosure" occurs that is "sufficient to put plaintiff on 'inquiry notice' so that he should have discovered the existence of his securities law claims." *Del Sontro v. Cendant Corp.*, 223 F. Supp. 2d 563, 573 (D.N.J. 2002); *In re Merrill Lynch Ltd. P'ships Litig.*, 7 F. Supp. 2d 256, 268 (S.D.N.Y. 1997) (finding that information "alerting [the plaintiff] to almost all of defendants' alleged misrepresentations, and that they had been misled through certain omissions" constituted inquiry notice), *aff'd*, 154 F.3d 56 (2d Cir. 1998).

As a result, and as the Court previously held in the January 25 Opinion, Plaintiffs and the class members cannot avoid being charged with inquiry notice of the alleged fraud, at a minimum, as of the publication FDA Staff Review Documents and the recommendation of the Arthritis Advisory Committee. *See In re Exxon Mobil*, 387 F. Supp. 2d at 418-19. However, Plaintiffs did not file their complaint until April 7, 2003, more than two years after the February 6, 2001 publication of the FDA Staff Review Documents and the Arthritis Advisory Committee public hearing on the following day.

January 25th ruling that the public disclosures made on February 6, 2001 were sufficient to put, and did put, Plaintiffs and the class members on inquiry notice of their claims as of that date.

The Court's January 25 Opinion was correctly based on the undisputed factual record that established that Plaintiffs, the class members and the entire market were on inquiry notice of the so-called "truth" regarding each of Defendants' alleged misstatements, at the latest, by February 6, 2001. The Briefing Document and the FDA Staff Review Documents publicly discussed all of the alleged misrepresentations about CLASS (*see* Dreier Decl., Ex. 1 ¶ 46), and the FDA Advisory Committee's recommendations and conclusions were publicized by the media and by securities analysts.[11] *See* Dreier Decl., Exs. 23, 47, 24, 26.

First, Plaintiffs allege that Defendants misrepresented the duration of CLASS as limited to six months. Dreier Decl., Ex. 1 ¶ 46. Although Defendants deny that they made any such misrepresentations, the fact that CLASS lasted longer than six months was publicly discussed as early as April 17, 2000, and, in no event, later than February 6, 2001. Pharmacia's April 17, 2000 press release specifically stated that CLASS was "an approximately 13-month study." Dreier Decl., Ex. 3. The Pink Sheet also specifically noted that CLASS was a "13-month double-blind . . . trial . . . . **Data from the first six months of the trial** were used for the head-to-head comparison of NSAIDs . . . ." Dreier Decl., Ex. 6 at 2 (emphasis added). If that were not enough to inform class members that CLASS lasted longer than six months, the Briefing Document and the Goldkind Review, posted on the FDA website on February 6, 2001, publicly reported that "[p]atients underwent Screening/Baseline visits and follow-up visits scheduled at 4, 13, 26, 39, and 52 weeks (and 65 weeks in protocol N49-98-02-035 only) after

[11] As Plaintiffs allege, Pharmacia common stock traded in an efficient market. Cmplt. ¶ 78. Accordingly, it cannot be disputed that the information in the Briefing Document and the FDA Staff Review Documents was immediately assimilated by the market. Indeed, both investment analysts and the general press reviewed the Briefing Document and the FDA Staff Review Documents promptly after they were posted and published reports about their content. *See* Dreier Decl., Exs. 16, 17, 18, 19, 20.

the first dose of study medication" (Dreier Decl., Ex. 12 at 18)[12]; and that "after the study ended the sponsor added a new set of analyses that was based on the first six months of study [sic] instead of the entire study period." Dreier Decl., Ex. 13 at 24.

Second, Plaintiffs allege that Defendants misrepresented the results of CLASS by analyzing the data using a combined endpoint of symptomatic ulcers in addition to ulcer complications, instead of using the pre-specified primary endpoint of ulcer complications alone. Dreier Decl., Ex. 1 ¶ 46. Although Defendants deny making any such misrepresentations with respect to the endpoint, the fact that Defendants used an expanded endpoint that was not pre-specified to analyze the data, was publicly disclosed no later than February 6, 2001, when Dr. Goldkind's report that "the inclusion of a combined analysis of CSUGIEs and GDU[13] **was a post-hoc decision** . . . " was posted on the FDA website. Dreier Decl., Ex. 13 at 21 (bold emphasis added; underscore in original).

Third, Plaintiffs allege that Defendants misrepresented the results of CLASS because the alternative analysis presented in JAMA was based upon only a comparison of Celebrex to the combined NSAIDs, while the original protocol called for both an analysis of the Celebrex vs. ibuprofen and diclofenac, combined, and then an analysis Celebrex vs. ibuprofen, and Celebrex vs. diclofenac, individually. Dreier Decl., Ex. 1 ¶ 46. Although Defendants deny making any such misrepresentations concerning the alternative analysis, the fact that the alternative analysis presented by Pharmacia was not pre-specified in the protocol for statistical analysis was publicly disclosed no later than February 6, 2001, when Dr. Goldkind publicly

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[12] The Briefing Document also contains multiple tables of comparative data which juxtapose data from the "Entire Study Period" with data from the "First Six Months." Dreier Decl., Ex. 12, at 98-103.

[13] "CSUGIE" is an acronym for Clinically Significant Upper Gastrointestinal Event and is synonymous with "ulcer complications," the predefined primary endpoint. "GDU" stands for gastroduodenal ulcers and is synonymous with "symptomatic ulcers," the secondary endpoint.

reported that the alternative analyses were "post hoc" and that the original protocol provided that Celebrex would satisfy the primary endpoint only if it was superior *both* to the NSAIDs pooled *and* to each of the NSAID comparators. *See* Dreier Decl., Ex. 13 at 7 ("comparisons to each of the NSAID comparators were defined in the original protocol," and "[t]he clinical importance of statistically significant superiority to each of the comparators was reflected in the statistical plans in the **original protocol**") (bold and underline emphasis in original).

Fourth, Plaintiffs allege that Defendants misrepresented the results of CLASS because "[a]nalyzing the CLASS Study data pursuant to the original protocol, meaning 12 and 15 months of data compared head-to-head and in combination for ulcer-related complications, Celebrex does not offer greater GI safety than traditional NSAIDs." Dreier Decl., Ex. 1 ¶ 46. Although Defendants deny making any such misrepresentations concerning the alternative analysis, the fact that CLASS did not demonstrate a statistically significant safety advantage for Celebrex over the NSAIDs on the basis of an analysis of the data from the entire study period according to the original protocol, was publicly disclosed no later than February 6, 2001. On that date, Dr. Witter's report that "Celecoxib did not demonstrate statistical superiority to NSAIDs (pooled) or either comparator (diclofenac or ibuprofen) with regards to the primary safety endpoint of CSUGIEs at any point in the trial although there were trends . . . that favored celecoxib" was posted on the FDA website. Dreier Decl., Ex. 14 at 82.

The allegations in the Complaint also confirm that no later than the February 6, 2001 posting of the Briefing Document and the FDA Staff Review Documents, Plaintiffs in the ""exercise of reasonable diligence should have discovered the basis for their claim" against the defendant.'" *Benak*, 435 F.3d at 400 (*quoting In re NAHC*, 306 F.3d at 1325) (other citations omitted). Indeed, the Complaint specifically alleges that "shortly" after the Briefing Document and the FDA Staff Review Documents were posted on the FDA website, Plaintiff's expert, James

Wright, "noted that ***the CLASS study lasted over twelve months, not six as discussed in the JAMA Article and that when all the data was considered, most or all of Celebrex's purported safety advantage disappeared.***" Dreier Decl., Ex. 1 ¶ 8 (bold and italics in original). Dr. Wright was not the only commentator to criticize the JAMA Article based upon a review of the data posed on the FDA website. *See* Dreier Decl., Ex. 42. Indeed, in his Expert Report submitted in connection with Plaintiffs' motion for class certification, Dr. Wright acknowledged that the so-called truth about each of the alleged factual misrepresentations set forth in the Complaint were revealed no later than February 6, 2001, when information about CLASS was posted on the FDA website:

> From the information available on the FDA's website on February 6, 2001, the astute observer could discern from the FDA reports that the CLASS study lasted longer than six months, and that data from the entire study period failed to demonstrate with statistical or clinical significance any GI safety advantage for Celebrex compared to diclofenac or ibuprofen, either with respect to the pre-determined primary endpoint of complicated ulcers or the combined endpoint of complicated and symptomatic ulcers. The FDA also discussed that Pharmacia's "combined" endpoint was a post-hoc, retrospective analysis, was not an endpoint of the CLASS study, and did not follow the study protocols.

Dreier Decl., Ex. 48 ¶ 22.[14]

As even Plaintiffs admit, the class was on inquiry notice of Defendants' alleged fraud no later than February 6, 2001. Because Plaintiffs did not file their Complaint until more than two years later, their claims are time-barred and must be dismissed as a matter of law.

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[14] There is no substantial dispute between the parties' respective experts regarding the extent of the factual information that was publicly available as of February 6, 2001. Dr. Wright's opinion echoed that of Defendants' expert, Dr. Timothy Wang, who offered his opinion that "the Briefing Document and the FDA Staff Review Documents that were posted on the FDA website, as well as the public statements made during the FDA Arthritis Advisory Committee hearing, publicly disclosed each of the alleged misrepresentations regarding the results of CLASS identified by Plaintiffs." Wang Decl.¶ 44.

CONCLUSION

For each of the reasons set forth above, Defendants' motion for summary judgment should be granted.

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Respectfully submitted,

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